Volume 1 of 2

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

STATE OF OREGON,
Plaintiff-Appellee,

v.

JOHN ASHCROFT, Attorney General, in his official capacity as United States Attorney General; ASA HUTCHINSON, in his official capacity as Administrator of the Drug Enforcement Administration; KENNETH W. MAGEE, in his official capacity as Director of the Drug Enforcement Administration, Portland Office; UNITED STATES OF AMERICA; UNITED STATES DEPARTMENT OF JUSTICE; UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,
Defendants-Appellants,

v.

PETER A. RASMUSSEN; DAVID MALCOLM HOCHHALTER; RICHARD HOLMES; JAMES ROMNEY; MELISSA BUSH; JOHN DOE #1,
Plaintiffs-Intervenors-Appellees.

No. 02-35587
D.C. No.
CV-01-01647-JO
OPINION

Appeal from the United States District Court
for the District of Oregon
Robert E. Jones, District Judge, Presiding

Argued and Submitted
May 7, 2003—Portland, Oregon

Filed May 26, 2004

Before: Donald P. Lay,* J. Clifford Wallace, and Richard C. Tallman, Circuit Judges.

Opinion by Judge Tallman;
Dissent by Judge Wallace

*Senior United States Circuit Judge for the Eighth Circuit, sitting by designation.

COUNSEL

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OPINION

TALLMAN, Circuit Judge:

A doctor, a pharmacist, several terminally ill patients, and the State of Oregon challenge an interpretive rule issued by Attorney General John Ashcroft which declares that physician assisted suicide violates the Controlled Substances Act of 1970 ("CSA"), 21 U.S.C. §§ 801-904. This so-called "Ashcroft Directive," published at 66 Fed. Reg. 56,607, criminal-

izes conduct specifically authorized by Oregon's Death With Dignity Act, Or. Rev. Stat. § 127.800-897. We hold that the Ashcroft Directive is unlawful and unenforceable because it violates the plain language of the CSA, contravenes Congress' express legislative intent, and oversteps the bounds of the Attorney General's statutory authority. *See* 5 U.S.C. § 706(2)(C), (D). The petitions for review are granted.

I

We have original jurisdiction over "final determinations, findings, and conclusions of the Attorney General" made under the CSA. 21 U.S.C. § 877. Because the Attorney General maintains that his interpretive rule is a "final determination" and because the Directive orders sanctions for violations of its provisions, we have original jurisdiction pursuant to § 877. *See Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1085 (9th Cir. 2003) (holding that an interpretive rule issued by the Attorney General pursuant to the CSA is a "final determination" for jurisdictional purposes because the rule "impos[es] obligations and sanctions in the event of violation [of its provisions]"); *see also City of Auburn v. Qwest*, 260 F.3d 1160, 1171-73 (9th Cir. 2001). We consider the matter transferred to us from the district court pursuant to 28 U.S.C. § 1631.[1]

[1]On April 17, 2002, United States District Judge Robert E. Jones entered a permanent injunction against enforcement of the Ashcroft Directive. 192 F. Supp. 2d 1077 (D. Or. 2002). Recognizing that he might lack jurisdiction over the matter, Judge Jones alternatively ordered the petitions for review transferred to us under 28 U.S.C. § 1631 ("Whenever a civil action is filed in a court . . . including a petition for review of administrative action . . . and that court finds that there is a want of jurisdiction, the court shall, if it is in the interest of justice, transfer such action or appeal to any other such court in which the action or appeal could have been brought at the time it was filed or noticed[.]"). 192 F. Supp. 2d at 1086-87. Although we conclude that the district court did not have jurisdiction, Judge Jones' opinion on the merits is well reasoned, and we ultimately adopt many of his conclusions.

This case is ripe for review because, under the Directive, health care practitioners risk criminal prosecution and loss of the privilege to prescribe medication if they choose to assist in the suicide of terminally ill patients pursuant to Oregon's Death With Dignity Act. *See Hemp Indus.*, 333 F.3d at 1086 ("[I]f . . . the challenged regulations present[ ] plaintiffs with the immediate dilemma to choose between complying with newly imposed, disadvantageous restrictions and risking serious penalties for violation, the controversy is ripe.") (citation omitted). "Because standing overlaps substantially with ripeness" in these circumstances, the petitioner health care practitioners have standing to challenge the Ashcroft Directive. *See id*.[2]

II

The Ashcroft Directive purports to interpret and implement the CSA, which Congress enacted as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970) (codified at 21 U.S.C. §§ 801-904). The stated purpose of the CSA is "to provide increased research into, and prevention of, drug abuse and drug dependence . . . and to strengthen existing law enforcement authority in the field of drug abuse." *Id.* at 1236 (preamble); *see also* H.R. Rep. No. 91-1444, *reprinted in* 1970 U.S.C.C.A.N. 4566, 4567 ("This legislation is designed to deal in comprehensive fashion with the growing menace of

[2]We need not decide whether the other plaintiffs also have standing. *See Leonard v. Clark*, 12 F.3d 885, 888 (9th Cir. 1993). However, we do note the argument by the plaintiff patients that the Ashcroft Directive, if followed, will achieve the in terrorem effect intended. Doctors will be afraid to write prescriptions sufficient to painlessly hasten death. Pharmacists will fear filling the prescriptions. Patients will be consigned to continued suffering and, according to the declarations of record, may die slow and agonizing deaths. Should patients attempt suicide without the assistance of their doctors and pharmacists, they may fail or leave loved ones with the trauma of dealing with the aftermath of certain forms of suicide too unpleasant to describe in this opinion.

drug abuse in the United States[.]"); *United States v. Moore*, 423 U.S. 122, 141 (1975); *Raich v. Ashcroft*, 352 F.3d 1222, 1228-29 (9th Cir. 2003); *United States v. Rosenberg*, 515 F.2d 190, 194 (9th Cir. 1975) (noting that the purpose of the CSA is to "counter drug abuse").

Under the CSA, it is unlawful to prescribe or dispense controlled substances without a federal registration. 21 U.S.C. § 841(a)(1); *see also id.* §§ 823(f), 822(a)(2). The CSA originally provided automatic federal registration for state-licensed health-care practitioners. § 303(f), 84 Stat. at 1255. The Attorney General could revoke a practitioner's federal registration only if the practitioner falsified his or her registration application, was convicted of a felony related to a controlled substance, or had his or her state license suspended or revoked. *Id.* § 304(a), 84 Stat. at 1255.

In 1971, pursuant to his authority to issue rules regulating controlled substances under the CSA, *see* 21 U.S.C. § 871(b), then-Attorney General John Mitchell promulgated the following regulation:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice . . . . An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of . . . the Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04 (originally designated as 21 C.F.R. § 306.04). This regulation exposed properly licensed and registered physicians to federal prosecution for distributing prescription drugs outside "the usual course of professional

practice." *See, e.g.*, *Moore*, 423 U.S. at 143 ("In practical effect, [Dr. Moore] acted as a large-scale 'pusher' not as a physician."); *Rosenberg*, 515 F.2d at 193 ("[A] doctor who acts other than in the course of professional practice is not a practitioner under the [CSA] and is therefore . . . . subject to the criminal provisions of the Act[.]") (citations omitted).

In 1984, Congress amended the CSA to give broader authority to the Attorney General. The Attorney General is now authorized to revoke a physician's prescription privileges upon his determination that the physician has "committed such acts as would render his registration . . . inconsistent with the public interest[.]" 21 U.S.C. § 824(a)(4). When determining which acts are inconsistent with the public interest, the Attorney General must consider the following factors:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority;
>
> (2) The applicant's expertise in dispensing . . . controlled substances;
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances;
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances;
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f). Although this provision gives the Attorney General new discretion over the registration of health care practitioners, Congress explained that "the amendment would continue to give deference to the opinions of State licencing authorities, since their recommendations are the first of the

factors to be considered[.]" S. Rep. No. 98-225, at 267 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3182, 3449.

Against this backdrop of federal regulation, in 1994, the State of Oregon enacted by ballot measure the country's first law authorizing physician assisted suicide. *See* Or. Rev. Stat. § 127.800-897. Oregon's Death With Dignity Act authorizes physicians to prescribe lethal doses of controlled substances to terminally ill Oregon residents according to procedures designed to protect vulnerable patients and ensure that their decisions are reasoned and voluntary. *See id.*[3] Oregon voters reaffirmed their support for the Death With Dignity Act on November 4, 1997, by defeating a ballot measure that sought to repeal the law.

Soon thereafter, several members of Congress, including then-Senator John Ashcroft, urged then-Attorney General Janet Reno to declare that physician assisted suicide violated the CSA. She declined to do so. In a letter dated January 5, 1998, Attorney General Reno explained that the CSA was not "intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice." She concluded that "the CSA does not authorize [the Drug Enforcement Administration ("DEA")] to prosecute, or to revoke DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law."[4]

[3]Under Oregon's Death With Dignity Act, only adult Oregon residents suffering from an incurable disease likely to result in death within six months are eligible for a lethal prescription. Or. Rev. Stat. 127.800 § 1.01(12); *id.* 127.805 § 2.01(1). A patient's diagnosis must be confirmed by two independent physicians. *Id.* 127.815 § 3.01; 127.820 § 3.02. Patients must sign a written request for the prescription in the presence of two witnesses attesting that the patient is competent and acting voluntarily. *Id.* 127.810 § 2.02.

[4]In response to Attorney General Reno's letter, members of Congress introduced bills to amend the CSA to explicitly authorize the Attorney General to revoke the registration of any practitioner who "intentionally

With a change of administrations came a change of perspectives. On November 9, 2001, newly appointed Attorney General John Ashcroft reversed the position of his predecessor and issued the Directive at issue here. The Ashcroft Directive proclaims that physician assisted suicide serves no "legitimate medical purpose" under 21 C.F.R. § 1306.04 and that specific conduct authorized by Oregon's Death With Dignity Act "may 'render [a practitioner's] registration . . . inconsistent with the public interest' and therefore subject to possible suspension or revocation." 66 Fed. Reg. at 56,608 (quoting 21 U.S.C. § 824(a)(4)). The Directive specifically targets health care practitioners in Oregon and instructs the DEA to enforce this determination "regardless of whether state law authorizes or permits such conduct by practitioners." *Id.*[5]

III

To be perfectly clear, we take no position on the merits or

dispensed or distributed a controlled substance with a purpose of causing, or assisting in causing, the suicide or euthanasia of any individual." H.R. 4006, 105th Cong. (1998) ("Lethal Drug Abuse Prevention Act of 1998"). The amendments failed. In 1999, Congress again declined to enact a similar proposed amendment. *See* H.R. 2260, 106th Cong. (1999) ("Pain Relief Promotion Act of 1999").

[5]The dissent argues that the Ashcroft Directive does not ban physician assisted suicide outright, but only bars the use of controlled substances for assisting suicide. This argument is wrong for two reasons. First, the Attorney General may revoke physician prescription privileges for any conduct appropriately deemed inconsistent with the public interest; such conduct need not involve controlled substances. *See* 21 U.S.C. § 824(a)(4). Second, it is clear to us that controlled substances provide the best and most reliable means for terminally ill patients to painlessly take their own lives. *See* Gerrit K. Kimsma, *Euthanasia and Euthanizing Drugs in The Netherlands*, *in* DRUG USE IN ASSISTED SUICIDE AND EUTHANASIA 193, 198-204 (Margaret P. Battin and Arthur G. Lipman eds., 1996); Kathy Farber-Langendoen and Jason H.T. Karlawish, *Should Assisted Suicide Be Only Physician Assisted?*, ANNALS INTERNAL MED., Mar. 21, 2000, at 482-87.

morality of physician assisted suicide. We express no opinion on whether the practice is inconsistent with the public interest or constitutes illegitimate medical care. This case is simply about who gets to decide. All parties agree that the question before us is whether Congress authorized the Attorney General to determine that physician assisted suicide violates the CSA. We hold that the Attorney General lacked Congress' requisite authorization. The Ashcroft Directive violates the "clear statement" rule, contradicts the plain language of the CSA, and contravenes the express intent of Congress.

A

[1] We begin with instructions from the Supreme Court that the "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide" belongs among state lawmakers. *Washington v. Glucksberg*, 521 U.S. 702, 735 (1997). In *Glucksberg*, Justice O'Connor emphasized that "[s]tates are presently undertaking extensive and serious evaluation of physician-assisted suicide. . . . In such circumstances, the . . . challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the 'laboratory' of the States . . . in the first instance." *Id.* at 737 (O'Connor, J., concurring) (citations and quotation marks omitted); *cf. Cruzan v. Director*, 497 U.S. 261, 293 (Scalia, J., concurring) ("[W]hen it *is* demonstrated . . . that a patient no longer wishes certain measures to be taken to preserve his or her life, it is up to the citizens [of the States] to decide, through their elected representatives, whether that wish will be honored."). Here, Oregon voters have twice declared their support for the legalization of physician assisted suicide in their state. We disagree with the dissent's suggestion that this court, rather than the Attorney General, is interfering with the democratic process. *See Glucksberg*, 521 U.S. at 735 ("Our holding permits this debate [about physician assisted suicide] to continue, as it should in a democratic society.").

The principle that state governments bear the primary responsibility for evaluating physician assisted suicide follows from our concept of federalism, which requires that state lawmakers, not the federal government, are "the primary regulators of professional [medical] conduct." *Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002); *see also Glucksberg*, 521 U.S. at 737 (O'Connor, J., concurring). The Supreme Court has made the constitutional principle clear: "Obviously, direct control of medical practice in the states is beyond the power of the federal government." *Linder v. United States*, 268 U.S. 5, 18 (1925); *see also Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power."). The Attorney General "may not . . . regulate [the doctor-patient] relationship to advance federal policy." *Conant*, 309 F.3d at 647 (Kozinski, J., concurring).[6]

[2] By criminalizing medical practices specifically authorized under Oregon law, the Ashcroft Directive interferes with Oregon's authority to regulate medical care within its borders and therefore "alter[s] the 'usual constitutional balance between the States and the Federal Government.' " *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991) (quoting *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985)). Under these circumstances, "[i]t is incumbent on the federal courts to be certain of Congress' intent" before finding that federal

[6]As noted in *Younger v. Harris*, 401 U.S. 37, 44-45 (1971):

> The concept [of federalism] does not mean blind deference to "States' Rights" any more than it means centralization of control over every important issue in our National Government and its courts. The Framers rejected both these courses. What the concept does represent is a system in which there is sensitivity to the legitimate interests of both State and National Governments, and in which the National Government, anxious though it may be to vindicate and protect federal rights and federal interests, always endeavors to do so in ways that will not unduly interfere with the legitimate activities of the States.

authority supercedes state law. *Gregory*, 501 U.S. at 460 (quotation marks and citation omitted).

[3] Unless Congress' authorization is "unmistakably clear," the Attorney General may not exercise control over an area of law traditionally reserved for state authority, such as regulation of medical care. *Id.* at 460-61 (quoting *Atascadero State Hosp.*, 473 U.S. at 242); *see also Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 173 (2001) ("This concern is heightened where an administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power."); *United States v. Bass*, 404 U.S. 336, 349 (1971) ("[U]nless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance."). In divining congressional intent, it is a "cardinal principle" of statutory interpretation that "where an otherwise acceptable construction of a statute would raise serious constitutional problems, [federal courts shall] construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988).

[4] The Ashcroft Directive is invalid because Congress has provided no indication—much less an "unmistakably clear" indication—that it intended to authorize the Attorney General to regulate the practice of physician assisted suicide. By attempting to regulate physician assisted suicide, the Ashcroft Directive invokes the outer limits of Congress' power by encroaching on state authority to regulate medical practice. *See Linder*, 268 U.S. at 18; *Conant*, 309 F.3d at 639. Because Congress has not clearly authorized such an intrusion, the Ashcroft Directive violates the clear statement rule. *See Solid Waste Agency*, 531 U.S. at 172-73; *Yeskey*, 524 U.S. at 208-09. We need not, and therefore do not, decide whether the Ashcroft Directive actually exceeds Commerce Clause boundaries, but only that it "invokes the outer limits of Congress'

power" without explicit authority from Congress. *Solid Waste Agency*, 531 U.S. at 172 (citing *Edward J. DeBartolo Corp.*, 485 U.S. at 575); *see also Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 208-09 (1998) ("[A]bsent an unmistakably clear expression of intent to alter the usual constitutional balance between the States and the Federal Government, we will interpret a statute to preserve rather than destroy the States' substantial sovereign powers.") (quotation marks and citations omitted).

B

The Ashcroft Directive not only lacks clear congressional authority, it also violates the plain language of the CSA. We hold that the Directive exceeds the scope of federal authority under the CSA, misconstrues the Attorney General's role under the statute, and fails to follow explicit instructions for revoking physician prescription privileges.

[5] The CSA expressly limits federal authority under the Act to the "field of drug abuse." Pub. L. No. 91-513, 84 Stat. 1236; 21 U.S.C. § 801(2)-(6). Contrary to the Attorney General's characterization, physician assisted suicide is not a form of drug "abuse" that Congress intended the CSA to cover.[7]

[7]The dissent argues that when Congress enacted the CSA it was not solely concerned with "drug abuse," as that term is commonly understood. The dissent suggests that a reference in the legislative record to "suicides and attempted suicides" and "drug-related deaths" indicates that Congress understood "drug abuse" to encompass physician assisted suicide. These excerpts are taken entirely out of context. In the record cited by the dissent, suicide is *distinguished* from "abuse," *see* H.R. Rep. No. 91-1444 (1970), 1970 U.S.C.C.A.N. at 4602, and statements concerning "drug-related deaths" clearly refer to overdoses from abuse of pharmaceutical drugs "diverted from the sick and injured to the black market." 130 Cong. Rec. 25,851 (1984) (statement of Rep. Rodino); 98 Cong. Rec. 365 (1984) (statement of Rep. Waxman). The record is voluminous and replete with statements of congressional intent to combat drug abuse and addiction, and particularly the problem of doctors who illicitly funnel prescription drugs into the hands of dealers and addicts. Both the Attorney General and the dissent expand the scope of the CSA in a manner that contravenes and distorts Congress' will.

Physician assisted suicide is an unrelated, general medical practice to be regulated by state lawmakers in the first instance. *Glucksberg*, 521 U.S. at 735, 737 (O'Connor, J., concurring).

[6] We know that Congress intended to limit federal authority under the CSA to the field of drug abuse because the statute's non-preemption clause provides that the CSA shall be not be construed to preempt state law unless there is a "positive conflict" between the text of the statute and state law. 21 U.S.C. § 903; *see also United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 502 (2001) (Stevens, J. concurring) ("[F]ederal courts [must], whenever possible, . . . avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a state have chosen to serve as a laboratory in the trial of novel social and economic experiments without risk to the rest of the country.") (citations and quotation marks omitted). No provision of the CSA directly conflicts with Oregon's Death with Dignity Act. However, the Attorney General's expansive interpretation of the CSA clearly conflicts with the Oregon law and therefore cannot be squared with the CSA's non-preemption clause. *See* 21 U.S.C. § 903; *see also Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997) ("As is always the case in our pre-emption jurisprudence, where federal law is said to bar state action in fields of traditional state regulation, . . . we have worked on the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.") (citation and quotation marks omitted).

To the limited extent that the CSA does authorize federal regulation of medical practice, Congress carefully circumscribed the Attorney General's role. The Attorney General may not define the scope of legitimate medical practice. *See* Pub. Law No. 91-513, 84 Stat. at 1241 (now codified at 42

U.S.C. § 290bb-2a).[8] In *Moore*, the Supreme Court held that the CSA "requires" the Secretary of Health and Human Services "to determine the appropriate methods of professional practice" under the statute. 423 U.S. at 144 (quoting 42 U.S.C. § 290bb-2a); *see also Rosenberg*, 515 F.2d at 194-95.

[7] The Attorney General, on the other hand, is authorized to revoke prescription privileges from physicians for conduct deemed "inconsistent with the public interest[.]" 21 U.S.C. § 824(a)(4). However, in this case, the Attorney General improperly invokes this authority. When determining what conduct is inconsistent with the public interest under the CSA, the Attorney General is required to consider five factors. *See* 21 U.S.C. § 823(f). The Attorney General reasons that physician assisted suicide is inconsistent with the public interest because the practice threatens public health. *See* Memorandum for the Attorney General from the Office of Legal Counsel, June 27, 2001 ("OLC Memo"), at 3-18.[9] Although threat to public health is one factor the Attorney General is to consider when determining the public interest, in this case he does not consider the other factors required by the statute. *See* 21 U.S.C. § 823(f).

The Attorney General misreads the CSA when he concludes that he may evaluate the public interest "based on *any*

[8]*See also* 21 U.S.C. § 811(b) ("The recommendations of the Secretary to the Attorney General [concerning which substances shall be covered by the CSA] shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug[.]"); 21 U.S.C. § 823(g)(2)(H)(i) ("Nothing in . . . regulations or practice guidelines [concerning the treatment of narcotic addicts] may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.").

[9]This memo is attached to the Ashcroft Directive and, according to the Attorney General, "sets forth the legal basis for my decision." 66 Fed. Reg. at 56,608.

of the five factors identified in the statute." OLC Memo at 3 (emphasis added). The CSA clearly provides that all five public interest factors "*shall* be considered." 21 U.S.C. § 823(f) (emphasis added). When the Attorney General declares that his Directive shall apply "regardless of whether state law authorizes or permits such conduct," he ignores the very first factor he is required to consider under the Act—*i.e.* "[t]he recommendation of the appropriate State licensing board or professional disciplinary authority." 21 U.S.C. § 823(f)(1). The Attorney General's categorical prohibition of physician assisted suicide also fails to consider the second and third public interest factors required under the CSA. *See* 21 U.S.C. § 823(f)(2), (3) (listing individual practitioner experience and criminal history as the second and third public interest factors).

Thus, we see at least three conflicts between the Ashcroft Directive and the text of the CSA. First, the Directive purports to regulate medical practices outside the field of drug abuse and prevention, despite the statute's limited scope and Congress' stated intent. Second, the Directive makes a unilateral medical determination that may not be made by the Attorney General.[10] Finally, the Directive evaluates public interest under 21 U.S.C. § 823 without considering all five factors required by that subsection. *See* 5 U.S.C. § 706(2)(C), (D) ("The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or] without observance of procedure required by law[.]").

[10]We do not intend to imply that the Secretary of Health and Human Services may determine that physician assisted suicide constitutes an illegitimate medical practice. As noted, by its terms the CSA is limited to "the field of drug abuse," which is not so broad as to include conduct authorized by Oregon's Death With Dignity Act. *See* Pub. L. No. 91-513, 84 Stat. 1236 (preamble) (1970).

C

[8] The CSA's legislative record confirms that the Attorney General has exceeded the scope of his authority. *See SEC v. McCarthy*, 322 F.3d 650, 655 (9th Cir. 2003) ("When the statute is ambiguous or the statutory language does not resolve an interpretive issue, our approach to statutory interpretation is to look to legislative history.") (citation and quotation marks omitted).

[9] Congress clearly intended to limit the CSA to problems associated with drug abuse and addiction. *See, e.g.,* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan. 23, 1970) ("[I]t cannot be overemphasized that the . . . [CSA] is designed to crackdown hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."). As we held in *Rosenberg*, "Congress was concerned with the diversion of drugs out of legitimate channels of distribution" when it enacted the CSA. 515 F.2d at 193. Congress acted to halt " 'the widespread diversion of [controlled substances] out of legitimate channels into the illegal market'[.]" *Id.* at 194 (quoting H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4572).

Furthermore, recognizing that this mandate may at times encroach on a state's traditional authority to regulate medical practices, Congress empowered "the principal health agency of the federal government," not the Attorney General, to make medical decisions under the Act. *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4581 ("[T]he committee is concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine. . . . In view of this situation, this section will provide guidelines, determined by the principal health agency of the federal government[.]"). In *Moore*, the Court observed that "Congress pointed out that criminal prosecutions *in the past* had turned on the opinions of federal prosecutors. Under the [CSA], those physicians who comply with the recommendations

made by the Secretary [of Health and Human Services] will no longer jeopardize their professional careers[.]" 423 U.S. at 144. (emphasis added) (quotation marks and citation omitted).

In 1974, Congress amended the CSA to "cure the present difficulty in [resolving] . . . the intricate and nearly impossible burden of establishing what is beyond the 'course of professional practice' for criminal law purposes." *Moore*, 423 U.S. at 140, n.16 (citation omitted). Although only tangentially related to this case, the 1974 amendment is noteworthy because it evinces Congress's intent to "preserve[ ] the distinctions found in the Controlled Substances Act between the functions of the Attorney General and the Secretary [of Health and Human Services]. . . . *All decisions of a medical nature are to be made by the Secretary [of Health and Human Services]*. Law enforcement decisions respecting the security of stocks of narcotic drugs and the maintenance of records on such drugs are to be made by the Attorney General." H.R. Rep. No. 93-884 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029, 3034 (emphasis added).

[10] Congress did not intend to expand the scope or general purpose of the CSA when it amended the statute in 1984 to give the Attorney General authority to revoke the federal registrations of physicians and pharmacists. *See* S. Rep. No. 98-225 at 260, 261-62, 1984 U.S.C.C.A.N. at 3443-44 ("In particular, the amendments . . . are intended to address the severe problem of diversion of drugs of legitimate origin into the illicit market."). Nor did Congress intend to grant the Attorney General any broader authority than he already exercised over the registration of manufacturers and distributers of controlled substances. *See id.* at 3449 ("The broader considerations for registration of practitioners set out in [the amendments] . . . are similar to those applicable under current law to registration applications on the part of manufacturers and distributors of controlled substances."). By enacting the 1984 amendments, Congress merely intended to close "loopholes" in the original legislation by authorizing the Attorney

General to revoke physician registrations without depending on state licencing boards, which had proven ineffective regulators of physicians who were diverting drugs into the illicit market. *See id.* at 3442-44.

[11] Finally, the legislative record demonstrates Congress' clear intent to prevent the Attorney General from revoking health care practitioners' DEA registrations on the sole basis of his decision that certain conduct "may threaten the public health and safety." *See* 21 U.S.C. § 823(f)(5). Congress unmistakably intended the Attorney General to consider all five factors under § 823(f) before determining whether physician conduct contravenes public interest. Congress specifically intended that the Attorney General must "continue to give deference to the opinions of the State licencing authorities," as their recommendations "are the first of the factors to be considered." S. Rep. No. 98-225 at 267, 1984 U.S.C.C.A.N. at 3449. It is undisputed that the Attorney General made no effort to solicit input from the State of Oregon before issuing his Directive, notwithstanding an express promise to do so by his subordinates within the United States Department of Justice.

D

The Ashcroft Directive proclaims that physician assisted suicide constitutes an illegitimate medical practice under 21 C.F.R. § 1306.04. Just as the Attorney General's interpretation of the text of the CSA conflicts with the statute's plain language and the clear intent of Congress, so too does his interpretation of this regulation.

[12] The Attorney General's interpretation of § 1306.04 exceeds the CSA's limited mandate to combat prescription drug abuse and addiction. *See* 21 U.S.C. § 801(2)-(6); Pub. L. No. 91-513, 84 Stat. 1236 (preamble); S. Rep. No. 98-225 at 260-62, 1984 U.S.C.C.A.N. at 3442-44; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; *Rosenberg*, 515 F.2d at

193-95. To the extent that the federal regulation of controlled substances impacts medical care, the Supreme Court in *Moore* articulated no role for the Attorney General in determining the appropriate methods of medical practice under § 1306.04. *See* 423 U.S. at 144. While the 1984 amendments to the CSA do extend the Attorney General's authority over federal registration of practicing physicians, these changes neither impact § 1306.04 nor provide the Attorney General the authority to determine the scope of legitimate medical practice in the manner attempted here.

IV

[13] Given the plain language of the CSA and its legislative record, we are under no obligation to defer to the Attorney General's interpretation of his role under the statute and its implementing regulations. *See Chevron U.S.A., Inc., v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984); *see also Solid Waste Agency*, 531 U.S. at 172-74. Agency determinations that squarely conflict with governing statutes are not entitled to deference. *Chevron*, 467 U.S. at 842-43. We "must, of course, set aside [agency] decisions which rest on an erroneous legal foundation." *NLRB v. Brown*, 380 U.S. 278, 291-92 (1965) (citation and quotation marks omitted); *cf. FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).

As already explained, the Ashcroft Directive exceeds the scope of the CSA and ignores the Attorney General's limited role. *See* Pub. L. No. 91-513, 84 Stat. 1236 (preamble); *see also* S. Rep. No. 98-225 at 260-62, 1984 U.S.C.C.A.N. at 3442-44. The Attorney General fails to follow the CSA's clear instructions when he declares that his assessment of the public interest may be based on "any" of the five factors required under § 823(f) and that his determination shall apply "regardless of whether state law authorizes or permits such conduct." *See* 21 U.S.C. § 823(f); *see also* S. Rep. No. 98-225 at 267, 1984 U.S.C.C.A.N. at 3449.

We also note that the Attorney General has no specialized expertise in the field of medicine and that he imposes a sweeping and unpersuasive interpretation of the CSA—which directly conflicts with that of his predecessor—without notice or comment. There is no reason to defer to his interpretation of his authority under the CSA. *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1994) (holding that an agency's interpretation may merit some deference in a field of its specialized expertise); *see also United States v. Mead Corp.*, 533 U.S. 218, 234-35 (2001).

[14] Nor shall we defer to the Attorney General's interpretation of 21 C.F.R. § 1306.04, which conflicts with the Supreme Court's interpretation of the same regulation in *Moore*. *See* 423 U.S. at 144; *see also Alhambra Hosp. v. Thompson*, 259 F.3d 1071, 1076 (9th Cir. 2001) (refusing to defer to an agency's interpretation of its own regulation when it conflicted with the "overriding intent" of Congress); *Maislin Indus., U.S., Inc. v. Primary Steel, Inc.*, 497 U.S. 116, 131 (1990) ("Once we have determined a statute's clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning.").

Citing federalism concerns, the Supreme Court recently refused to defer to an agency's interpretation of its own regulations without clear authority from Congress. *See Solid Waste Agency*, 531 U.S. at 172-74. As already explained, the Attorney General's interpretation of § 1306.04 permits him to override state regulation of general medical practices *despite* Congress' express intent to limit federal authority under the CSA to the field of drug abuse and addiction. *See* Pub. L. No. 91-513, 84 Stat. 1236 (preamble); 21 U.S.C. § 801. Clearly, "our deference does not extend to agencies' constructions

which conflict with statutory directives." *Pacific Coast Med. Enter. v. Harris*, 633 F.2d 123, 131 (9th Cir. 1980).[11]

V

[15] In sum, the CSA was enacted to combat drug abuse. To the extent that it authorizes the federal government to make decisions regarding the practice of medicine, those decisions are delegated to the Secretary of Heath and Human Services, not to the Attorney General. The Attorney General's unilateral attempt to regulate general medical practices historically entrusted to state lawmakers interferes with the democratic debate about physician assisted suicide and far exceeds

[11]The Supreme Court has also refused to extend deference to an agency's interpretation of a regulation when, as here, it conflicts with the agency's previous interpretation of the same regulation. *See Norfolk S. Railway Co. v. Shanklin*, 529 U.S. 344, 356 (2000) ("[N]o . . . deference is appropriate [because] [n]ot only is the [agency's] interpretation inconsistent with the text of [the regulation], but *it also contradicts the agency's own previous construction*[.]") (emphasis added); *Solid Waste Agency*, 531 U.S. at 168 (noting that the agency's new interpretation is unsupported by any "evidence that the [agency] mistook Congress' intent" the first time); *see also Pacific Coast Med. Enter.*, 633 F.2d at 131 ("The [regulation] must be reasonably susceptible to the construction placed upon them by the [agency], both on [its] face *and in light of [its] prior interpretation and application*.") (emphasis added).

Nor is deference due when an agency's interpretation of a regulation conflicts with the agency's intent at the time the regulation was promulgated. *See Thomas Jefferson Univ. Hosp. v. Shalala*, 512 U.S. 504, 512 (1994) (quoting *Gardebring v. Jenkins*, 485 U.S. 415, 430 (1988)). Here, the Attorney General asserts that the CSA and its implementing regulations must reflect a uniform federal standard of practice. But when Attorney General Mitchell promulgated 21 C.F.R. § 1306.04 in 1971, physicians were entitled to distribute controlled substances—as a matter of right—merely by complying with *state* law. *See* Pub. L. No. 91-513, 84 Stat. 1253, 1255 (§§ 303(f), 304(a)). Neither Congress nor Attorney General Mitchell could have intended § 1306.04 to empower the Attorney General to enforce a uniform federal standard of medical care, as contemplated here, when authorization to prescribe drugs under the CSA turned on the decisions of state licensing and law enforcement authorities. *See id.*

the scope of his authority under federal law. We therefore hold that the Ashcroft Directive is invalid and may not be enforced.

The petitions for review are GRANTED. The injunction previously entered by the district court is ORDERED continued in full force and effect as the injunction of this court.

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WALLACE, Senior Circuit Judge, dissenting:

As my colleagues in the majority suggest, this case is not about the ethics or public policy implications of physician-assisted suicide. We need not decide whether the federal government or the states is better equipped to regulate physician-assisted suicide. Setting aside the public policy aspects of physician-assisted suicide that evoke passionate feelings, this case involves a single legal question: is the Attorney General's interpretation of 21 C.F.R. § 1306.04(a) entitled to deference? Because our past decisions command deference to the Attorney General's interpretive rule, I would deny the petition for review on the merits.

I.

The Oregon Death with Dignity Act (Oregon Act) provides that a capable adult who "has been determined by the attending physician and consulting physician to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die, may make a written request for medication for the purpose of ending his or her life in a humane and dignified

manner." OR. REV. STAT. § 127.805(1). Once various safeguards have been satisfied, the attending physician may "writ[e] a prescription for medication to enable a qualified patient to end his or her life," *id.* § 127.815(1)(k), and the attending physician, the pharmacist, or a third person may dispense the medication to the patient, *id.* § 127.815(1)(L). To date, Oregon is the only state that has passed legislation expressly legalizing physician-assisted suicide.

By authorizing physicians to prescribe and dispense controlled substances for the purpose of assisting suicide, the Oregon Act arguably draws Oregon law into tension with the federal Controlled Substances Act, 21 U.S.C. §§ 801-971. "Except as authorized by [the Controlled Substances Act]," it is unlawful for any person—including physicians—to "manufacture, distribute, or dispense" a controlled substance. 21 U.S.C. § 841. The Controlled Substances Act permits physicians to dispense controlled substances only if they have previously registered with the Attorney General. *Id.* §§ 822(a)(2), 823(f). Even registered physicians may not distribute controlled substances, however, without first issuing a "prescription," *id.* § 829(a), which, "to be effective[,] must be issued for a legitimate medical purpose," 21 C.F.R. § 1306.04(a). The Attorney General may revoke or suspend a physician's registration if the registrant has been convicted of violating the Controlled Substances Act, 21 U.S.C. § 824(a)(2), or has committed acts "inconsistent with the public interest," *id.* §§ 823(f), 824(a)(4).

Whether physician-assisted suicide is "a legitimate medical purpose" and "consistent with the public interest" has been the subject of considerable public debate. In a letter dated November 5, 1997, Drug Enforcement Administration (DEA) Administrator Thomas A. Constantine opined that assisting suicide is not a "legitimate medical purpose" under the Controlled Substances Act. Letter from Constantine, DEA Administrator, to Henry J. Hyde, Congressman (Nov. 5, 1997), *available at* http://www.house.gov/judiciary/

constantine.htm. Seven months later, however, then-Attorney General Janet Reno rejected the DEA Administrator's opinion letter, concluding that "the [Controlled Substances Act] does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law." Statement of Attorney General Reno on Oregon's Death with Dignity Act (June 5, 1998), *available at* http://www.usdoj.gov/opa/pr/1998/June/259ag.htm.html. General Reno's interpretation of the Controlled Substances Act prompted a stern letter from several Senators—including then-Missouri Senator John Ashcroft:

> [T]here is agreement among all three branches of the Federal government that assisted suicide is not a legitimate medical practice. The DEA is therefore on solid ground in concluding that "delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a 'legitimate medical purpose,' " and that such a misuse of drugs warrants the revocation of a physician's license to dispense controlled substances.

Letter from John Ashcroft et al., U.S. Senators, to Janet Reno, Attorney General (Dec. 19, 1997).

Following his appointment to head the Department of Justice, General Ashcroft issued an interpretive rule on November 9, 2001, reversing his predecessor's earlier position regarding physician-assisted suicide. Dispensing of Controlled Substances To Assist Suicide (Ashcroft Directive), 66 Fed. Reg. 56,607 (Nov. 9, 2001) (to be codified at 21 C.F.R. pt. 1306). The Ashcroft Directive states that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001)" and that a physician who prescribes controlled substances to assist suicide "may 'render his registration . . . inconsistent with the public interest' " and thereby risk suspension or revocation of his registration under 21

U.S.C. § 824(a)(4). *Id.* at 56,608. General Ashcroft directed "the DEA, effective upon publication of this memorandum in the Federal Register, to enforce and apply this determination, notwithstanding anything to the contrary in the June 5, 1998, Attorney General's letter." *Id.*

Before the Department of Justice took action to enforce the Ashcroft Directive, a group of physicians, patients, and the state of Oregon (collectively Petitioners) brought this action in federal district court, seeking declaratory and injunctive relief. Although the district court lacked jurisdiction to consider the petition for review, *see Pac. Power & Light Co. v. Bonneville Power Admin.*, 795 F.2d 810, 814-16 (9th Cir. 1986); *UMC Indus., Inc. v. Seaborg*, 439 F.2d 953, 955 (9th Cir. 1971) (per curiam), this court has jurisdiction pursuant to 28 U.S.C. § 1631 and 21 U.S.C. § 877.

II.

The Petitioners do not dispute that the Controlled Substances Act prohibits physicians from dispensing and prescribing controlled substances except for legitimate medical purposes. *See* 21 C.F.R. § 1306.04(a) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose . . . ."); *United States v. Moore*, 423 U.S. 122, 124 (1975) (holding that physicians violate the Controlled Substances Act "when their activities fall outside the usual course of professional practice"); *United States v. Kaplan*, 895 F.2d 618, 619 (9th Cir. 1990) (stating that the Controlled Substances Act prohibits "prescribing controlled substances for reasons other than legitimate medical purposes"); *United States v. Rosenberg*, 515 F.2d 190, 193 (9th Cir. 1975) (interpreting the Controlled Substances Act "to mean that a doctor who acts [outside] the course of professional practice is not a practitioner under the Act and is therefore not authorized to prescribe controlled substances"). Instead, they argue that the Ashcroft Directive is not a valid agency rule—and thus is not entitled to deference—for the

following four reasons: (1) the Attorney General did not promulgate the Ashcroft Directive pursuant to the Administrative Procedure Act's (APA) notice-and-comment rulemaking procedures; (2) the Ashcroft Directive violates the Controlled Substances Act's non-preemption provision; (3) the Ashcroft Directive exceeds the scope of the Attorney General's authority under the Controlled Substances Act; and (4) the Ashcroft Directive is an arbitrary and capricious agency action. As will be seen, none of these creative challenges to the Ashcroft Directive withstands close scrutiny or justifies the majority's departure from our customary canons of deference to agency action.

A.

Petitioners argue first that deference to the Ashcroft Directive is not warranted because the Attorney General did not satisfy the APA's notice-and-comment rulemaking procedures. *See* 5 U.S.C. § 553 (requiring that agencies give "interested persons" notice of proposed rules and "an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation"). The United States counters that the APA does not require notice and comment here, because the Ashcroft Directive is an interpretive rule, not a legislative rule. *See id.* § 553(b)(3)(A) (stating the APA's notice-and-comment procedures do not ordinarily apply to interpretive rules). If the Ashcroft Directive is "genuinely an interpretive rule, it is valid despite the absence of notice and comment procedures." *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1087 (9th Cir. 2003).

We distinguish interpretive and legislative rules by asking (1) whether, absent the rule, there would be an inadequate legislative basis for an enforcement action; (2) whether the agency "explicitly invoked its general legislative authority"; and (3) whether "the rule effectively amends a prior legislative rule." *Id.* "If the answer to any of these questions is affir-

mative, we have a legislative, not an interpretive rule." *Sweet v. Sheahan*, 235 F.3d 80, 91 (2d Cir. 2000), *quoting Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993).

The Ashcroft Directive does not bear any of these three hallmarks of a legislative rule. First, even absent the Ashcroft Directive, the Attorney General could bring an enforcement action because the Controlled Substances Act itself prohibits distributing a controlled substance without a prescription, 21 U.S.C. § 829(a), and preexisting Department of Justice regulations declare that "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose," 21 C.F.R. § 1306.04(a). Second, the Attorney General did not expressly invoke his statutory authority to "promulgate . . . any [legislative rules] . . . which he may deem necessary and appropriate for the efficient execution of his functions under" the Controlled Substances Act. 21 U.S.C. § 871(b). Third, although the Ashcroft Directive contradicts former-Attorney General Reno's 1998 statement, the Ashcroft Directive is not inconsistent with any *legislative* rule. *See Chief Prob. Officers of Cal. v. Shalala*, 118 F.3d 1327, 1337 (9th Cir. 1997) (holding that an interpretive rule can amend an interpretive rule); Richard J. Pierce, Jr., *Distinguishing Legislative Rules from Interpretative Rules*, 52 ADMIN. L. REV. 547, 566-73 (2000) (discussing this principle).

The Ashcroft Directive does not purport to "create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress." *Hemp*, 333 F.3d at 1087. Instead, like other interpretive rules, the Ashcroft Directive is "essentially hortatory and instructional," clarifying what the Controlled Substances Act means when applied to a narrowly defined situation. *Alcaraz v. Block*, 746 F.2d 593, 613 (9th Cir. 1984); *see also Hemp*, 333 F.3d at 1087 (explaining that interpretive rules "explain, but do not add to, the substantive law that already exists in the form of a statute or legislative rule"). Thus, General Ashcroft's failure to give

Petitioners advance notice and an opportunity to comment does not invalidate the Ashcroft Directive.

B.

The Petitioners next contend that the Ashcroft Directive violates 21 U.S.C. § 903, the Controlled Substances Act's non-preemption clause. Section 903 reads:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903. The Petitioners argue that the Ashcroft Directive construes the Controlled Substances Act to preempt the Oregon Act and that this result violates 21 U.S.C. § 903 because there is no "positive conflict" between the Controlled Substances Act's text and the Oregon Act.

Petitioners are wrong; the Ashcroft Directive is consistent with section 903 because it does not utterly exclude state regulation of medical practice or even state regulation of physician-assisted suicide. The Ashcroft Directive does not effect a "positive conflict" with state law because it does not make "the federal role . . . so pervasive that no room is left for the states to supplement it." *Sayles Hydro Assocs. v. Maughan*, 985 F.2d 451, 455 (9th Cir. 1993). States may supplement the Ashcroft Directive by expanding the Controlled Substances Act's prohibitions, providing additional civil or criminal sanctions against physicians who assist suicide, or permitting conduct that the Ashcroft Directive does not prohibit.

More relevant for present purposes, the Ashcroft Directive proscribes only one method of assisting suicide: prescription, dispensation, and administration of controlled substances. The majority vastly exaggerates the Ashcroft Directive's scope by intimating that it "ban[s] physician-assisted suicide outright." A closer examination of the Ashcroft Directive's text reveals that "[assisting] suicide is not a 'legitimate medical purpose' " only "*within the meaning of 21 C.F.R. § 1306.04*" (prescription of controlled substances). Ashcroft Directive, 66 Fed. Reg. at 56,608 (emphasis added). The Ashcroft Directive avoids the sweeping prohibition claimed by the majority by assiduously limiting its reach to controlled substances; under its plain terms, only applications involving *controlled substances* may "render [a physician's] registration . . . inconsistent with the public interest" and therefore subject to revocation. *Id.*, *quoting* 21 U.S.C. § 824(a)(4). Oregon physicians may continue to assist suicide by other means without risking suspension or revocation of their registration to prescribe controlled substances. *See* George J. Annas, *The "Right To Die" in America: Sloganeering from* Quinlan *and* Cruzan *to* Quill *and* Kevorkian, 34 DUQ. L. REV. 875, 891 (1996) (discussing carbon monoxide as an alternative to controlled substances); Jeffrey G. Sherman, *Mercy Killing and the Right To Inherit*, 61 U. Cin. L. Rev. 803, 834 (1993) (same). The Ashcroft Directive does not, therefore, "occupy the field" of physician-assisted suicide in violation of section 903. *See United States v. Leal*, 75 F.3d 219, 227 (6th Cir. 1996) (holding that "there is no such conflict" between 21 C.F.R. § 1306.04 and state law).

C.

Petitioners maintain—and the majority agrees—that the Ashcroft Directive is not entitled to deference because the Attorney General promulgated it "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

1.

The Ashcroft Directive is not entitled to deference, the majority contends, because "Congress intended to limit federal authority under the [Controlled Substances Act] to the field of drug abuse" while preserving states' discretion to authorize other life-threatening applications of controlled substances. By what authority? True, the Controlled Substances Act's preamble arguably manifests Congress's intent "to strengthen existing law enforcement authority in the field of drug abuse," Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, pmbl., 84 Stat. 1236, 1236, but it does not "expressly limit[ ] federal authority under the Act" to mainstream drug abuse, as the majority argues. Moreover, there is simply no textual support for the majority's conclusory assertion that "the field of drug abuse," as discussed in the Controlled Substances Act, does not encompass drug-induced, physician-assisted suicide.

The Controlled Substances Act's text furnishes ample evidence that Congress was concerned not only with street-variety drug trafficking and abuse but also with any other improper drug use that might have a "detrimental effect on the health and general welfare of the American people." 21 U.S.C. § 801(2). The Act targets all "improper use of controlled substances," *id.*, and gives the Attorney General discretion to decide whether registering a physician to dispense drugs is "consistent with the public health and safety," *id.* § 823(b)(5). Reasonable minds might disagree as to whether physician-assisted suicide constitutes an "improper use" of a controlled substance, but nothing in the Controlled Substances Act's text precludes its application to physician-assisted suicide.

Lacking a textual hook for its position, the majority attempts to patch the holes in its argument with inconclusive fragments of legislative history. Discerning congressional intent from legislative history is a speculative enterprise under

the best of circumstances, and the risk of error is compounded in a case such as this when legislators' published statements do not squarely address the question presented—i.e., whether Congress intended to exclude drug-induced, physician-assisted suicide from regulation under the Controlled Substances Act. *See Chisom v. Roemer*, 501 U.S. 380, 406 (1991) (Scalia, J., dissenting) ("We are here to apply the statute, not legislative history, and certainly not the absence of legislative history.").

The Controlled Substances Act's legislative history suggests that some members of Congress envisioned the physician-registration provisions primarily as a mechanism to stem the flow of controlled substances into illicit channels, *Moore*, 423 U.S. at 135, but the record also specifically identifies "suicides and attempted suicides" as a "[m]isuse of a drug." H.R. REP. NO. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4572; *see also Dangerous Drug Diversion Control Act of 1984: Hearing on H.R. 5656 Before the House Subcomm. on Health and the Env't*, 98th Cong. 365 (1984) (statement of Rep. Henry A. Waxman, Chairman, House Subcomm. on Health and the Env't) (expressing concern that "[d]rugs legally manufactured for use in medicine are responsible for a substantial majority of drug-related deaths"); 130 CONG. REC. 25,851 (statement of Rep. Rodino) (1984) (reporting that "diversion" of prescription drugs "is responsible for 70 percent of the deaths and injuries due to all drug abuse"). Viewed holistically, the record "does not demonstrate a clear and certain congressional intent" to preclude physician-assisted suicide from regulation under sections 823 and 824. *Rust v. Sullivan*, 500 U.S. 173, 190 (1991). Controlling precedent thus compels the conclusion that the Controlled Substances Act's "legislative history . . . cannot form the basis for enjoining [the Attorney General's] regulation[ ]." *Id.*; *see also Student Loan Fund of Idaho, Inc. v. U.S. Dept. of Educ.*, 272 F.3d 1155, 1165 (9th Cir. 2001) (applying this principle in an analogous setting).

2.

The majority asserts that the Attorney General lacks authority to decide whether physician-assisted suicide is consistent with "the public interest" and a "legitimate medical practice" under the Controlled Substances Act and its implementing regulations because Congress intended to preserve the states' traditional authority to make these determinations. This argument ignores the Controlled Substances Act's text and controlling Supreme Court decisions.

It is axiomatic that the meaning of federal law is a federal question. *See Reconstr. Fin. Corp. v. Beaver County*, 328 U.S. 204, 208 (1946) ("What meaning Congress intended is a federal question we must determine."). Although federal law occasionally incorporates state-law definitions by reference, *see, e.g.*, *De Sylva v. Ballentine*, 351 U.S. 570, 580-82 (1956) (defining the word "children" in a federal statute according to state law), recourse to state law is the exception rather than the norm. "[I]n the absence of a plain indication to the contrary, . . . Congress when it enacts a statute [does] not mak[e] the application of the federal act dependent on state law." *Miss. Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989) (quoting *Jerome v. United States*, 318 U.S. 101, 104 (1943)); *Kahn v. INS*, 36 F.3d 1412, 1414 (9th Cir. 1994) (per curiam) (same).

State law may be *relevant* to certain provisions of the Controlled Substances Act, *see, e.g.*, 21 U.S.C. § 823(f) (instructing the Attorney General to consider state-law violations when deciding whether a physician's registration would be contrary to the public interest), but nothing in the Controlled Substances Act plainly evinces a congressional intent to define "the public interest" solely according to state law. On the contrary, section 823 instructs the Attorney General to identify acts "inconsistent with the public interest" by reference to a variety of sources, including a physician's federal conviction record, compliance with "Federal . . . laws relating

to controlled substances," and "other conduct which may threaten public health and safety." *Id.* The majority's contention that the Attorney General cannot suspend or revoke a physician's registration without state authorization ignores *Mississippi Band*'s "plain indication" rule and contravenes Congress's clearly expressed intent.

The majority also cites *Washington v. Glucksberg*, 521 U.S. 702, 735, 737 (1997) (O'Connor, J., concurring), for the position that the Attorney General must defer to the Oregon Act because "[p]hysician-assisted suicide is an unrelated, general medical practice to be regulated by the States in the first instance." *Glucksberg*, however, addressed states' authority to *prohibit* physician-assisted suicide *in the absence of federal regulation*; the case did not answer the question whether Congress may exercise its Commerce Clause power to deny physicians access to controlled substances for physician-assisted suicide. Rather than place federalism limitations on the federal government's authority to restrict physician-assisted suicide, Justice O'Connor's concurring opinion stressed that "[t]here is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill . . . individuals . . . and the State's interests in protecting those who might seek to end life mistakenly or under pressure." *Id.* at 737. Simply put, courts should defer to the political process instead of interposing hasty constitutional constraints.

Glucksberg does not require the Attorney General to interpret the Controlled Substances Act and its implementing regulations according to state standards of professional conduct. Rather, the Supreme Court's decision stands for the broader proposition that federal courts generally should keep their distance, allowing the political process to decide whether and how to regulate physician-assisted suicide. The majority's shortsighted decision to declare the Ashcroft Directive invalid has precisely the opposite effect.

3.

As an alternative, the majority contends that the Secretary of Health and Human Services (Secretary)—not the Attorney General—should decide whether medical practices are "legitimate" and consistent with the "public interest" under the Controlled Substances Act and its implementing regulations. The Controlled Substances Act's text directly contradicts this argument: "*The Attorney General* may deny an application for . . . registration [of a practitioner to dispense drugs] if *he determines* that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. § 823(f) (emphasis added). Congress could not have stated more plainly that the Attorney General, not the Secretary, has authority to determine whether a physician's registration is consistent with the public interest.

The majority's reading of section 823 is a particularly astonishing exercise in statutory construction because the Controlled Substances Act specifically provides for the Secretary's participation in other discretionary judgments. *See, e.g.*, 21 U.S.C. § 811(b) (providing that the Secretary's determination with respect to the classification of controlled substances "shall be binding on the Attorney General"); *id.* § 823(f) (authorizing the Secretary to evaluate a practitioner's "qualifications and competency" to perform "research with controlled substances"); *id.* (stating that the Secretary "shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of . . . controlled substances from legitimate medical or scientific use"); *id.* § 823(g)(2)(H)(i) (empowering the Secretary to "issue regulations . . . or issue practice guidelines" for the approval of "additional credentialing bodies"). When Congress wished to entrust a discretionary judgment to the Secretary it said so explicitly. The Controlled Substances Act conspicuously omits any reference to the Secretary, however, when discussing the Attorney General's authority to assess "the public interest" for purposes of ordinary physician registrations. *Id.* § 823(f). The explanation

for this omission is perfectly clear: section 823 authorizes the Attorney General—not the Secretary—to decide whether a physician's registration is consistent with the public interest.

The majority asserts that under the Controlled Substance Act all standards of legitimate professional conduct are set by the Secretary, not by the Attorney General. The majority's argument relies on a section of the Act entitled "Medical Treatment of Narcotic Addiction," which is located in a different title of the legislation. This section provides that the Secretary, "after consultation with the Attorney General . . ., shall determine the appropriate methods of professional practice in the medical treatment of . . . *narcotic addiction*." 42 U.S.C. § 290bb-2a (emphasis added). Obviously, this is irrelevant to the issue before us. Yet from this narrow provision, the majority draws the sweeping, untenable conclusion that the Attorney General cannot enforce the Controlled Substances Act against a physician unless the Secretary first concludes that the prescription did not issue for a "legitimate medical purpose."

The Supreme Court rejected a similar challenge to the Attorney General's interpretive authority in *Moore*. The Court explained that Congress designed subsection 290bb-2a to function only as a limited safe-harbor for physicians who prescribe controlled substances to drug addicts; as long as physicians employ the treatment methods outlined in the Secretary's published standards of professional practice, the Attorney General may not prosecute them under the Controlled Substances Act. *Moore*, 423 U.S. at 144. The Court recognized, however, that "[t]he negative implication [of this provision] is that physicians who go beyond approved practice remain subject to serious criminal penalties." *Id.* In other words, section 290bb-2a prevents the Attorney General from enforcing the Controlled Substances Act and its implementing regulations only when the Secretary declares that a specific *narcotic addiction treatment* serves a "legitimate medical purpose."

We confirmed *Moore*'s reading of subsection 290bb-2a in *Rosenberg*, holding that the Attorney General may enforce the Controlled Substances Act against physicians whose practices do not qualify for protection under the Secretary's specific safe-harbor guidelines. We explained that the Secretary's authority to

> determine the appropriate method of professional practice in the medical treatment of narcotic addiction . . . was adopted in light of Congress' awareness that there had been criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of Federal prosecutors. *The committee evidenced no intention to restrict such prosecutions*. Indeed[,] *they seemed to think* [*these prosecutions*] *would continue*, but that some standards of professional practice should be established so that . . . physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers by accepting narcotic addicts as patients.

515 F.2d at 194-95 (emphasis added) (internal quotations omitted), *citing* H.R. REP. NO. 91-1444, *reprinted in* 1970 U.S.C.C.A.N. at 4581 (observing that "for the last 50 years" federal officials have "determine[d] the appropriate method of the practice of medicine . . . through . . . criminal prosecution[s]" and suggesting that these prosecutions should continue subject to the Secretary's limited guidelines for treatment of narcotic addiction); *see also* H.R. REP. NO. 93-884 (1974), *reprinted in* 1974 U.S.C.C.A.N. 3029, 3034 (recognizing that "[t]he registration required under [the section of the Controlled Substances governing treatment of narcotic addiction] is *separate and distinct* from regular registration under the Controlled Substances Act," which is administered by the Attorney General (emphasis added)).

Here the Petitioners have not shown and do not contend that the Secretary's guidelines approve physician-assisted sui-

cide as an "appropriate method[ ] of professional practice in the medical treatment of . . . *narcotic addiction*." 42 U.S.C. § 290bb-2a (emphasis added). As such, subsection 290bb-2a's safe-harbor rule does not apply, and the Attorney General was not required to consult the Secretary prior to issuing his determination that physician-assisted suicide does not constitute a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a).

4.

The majority maintains that even if the Controlled Substances Act authorizes the Attorney General to ascertain whether physician-assisted suicide is "inconsistent with the public interest," General Ashcroft abused his discretion in this case by failing to consider all five factors outlined in 21 U.S.C. § 823(f). Subsection (f) provides in part that "[i]n determining the public interest, the following factors shall be considered":

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

28 U.S.C. § 823(f). The Ashcroft Directive is invalid, the majority argues, because General Ashcroft "made no effort to

solicit input from the State of Oregon before issuing" the interpretive rule.

Contrary to the majority's assertion, the Ashcroft Directive does not sidestep subsection 823(f)'s five-factor inquiry. The Justice Department has yet to initiate an enforcement action against any individual physician pursuant to section 824, so the hour has not arrived for the Attorney General to consider subsections 823(f)(1)-(4) (i.e., the state licensing board's recommendation and physicians' relevant experience and criminal record). The Ashcroft Directive merely cautions that a physician who prescribes controlled substances to assist suicide "*may* 'render his registration . . . inconsistent with the public interest," Ashcroft Directive, 66 Fed. Reg. at 56,608 (emphasis added); it does not declare that assisting suicide *shall* render a physician's registration inconsistent with the public interest. This word choice is significant, because it conclusively refutes the majority's contention that assisting suicide *automatically* renders a physician's registration "inconsistent with the public interest" under the Ashcroft Directive. Even if "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001)," the Attorney General remains free to consult all of section 823's five factors—including the recommendation of Oregon's licensing board or disciplinary authority—before making a final decision whether to suspend or revoke a particular physician's registration.

Significantly, the Ashcroft Directive's warning that assisting suicide could prompt Controlled Substances Act enforcement actions comports with fundamental administrative law principles:

> When a governmental official is given the power to make discretionary decisions under a broad statutory standard [e.g., "the public interest"], case-by-case decisionmaking may not be the best way to assure fairness. Here the [Attorney General] . . . sought to

> define the statutory standard . . . by the use of his rulemaking authority. The decision to use objective rules in this case provides [physicians] with more precise notice of what conduct will be sanctioned and promotes equality of treatment among similarly situated [individuals].

Dixon v. Love, 431 U.S. 105, 115 (1977). The Controlled Substances Act facilitates adherence to these principles by expressly authorizing the Attorney General to "promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter." 21 U.S.C. § 871. Thus, General Ashcroft acted well within the scope of his statutory authority in declaring that assisting suicide does not serve a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a) and that this practice "may 'render [a physician's] registration . . . inconsistent with the public interest' and therefore subject to possible suspension or revocation under [section] 824." Ashcroft Directive, 66 Fed. Reg. at 56,608.

5.

Finally, the majority argues that the Ashcroft Directive exceeds the Attorney General's statutory authority because Congress has not clearly authorized the Attorney General to upset the delicate balance between federal regulation of controlled substances and state control of medical practices. As support for this conclusion, the majority invokes the Supreme Court's recent analysis in *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159 (2001):

> Where an administrative interpretation of a statute invokes the outer limits of Congress' power, we expect a clear indication that Congress intended that result. This requirement stems from our prudential

> desire not to needlessly reach constitutional issues and our assumption that Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority. This concern is heightened where the administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power.

Id. at 172-73 (internal citations omitted), *citing Edward J. DeBartalo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988). *See generally id.* at 172-74 (refusing to afford deference to an agency regulation that raised a serious constitutional issue where there was no indication in the statute that Congress intended to encroach on traditional state powers over land and water use). Although the Court addressed the validity of "an administrative interpretation of a *statute*," *id.* at 172 (emphasis added), its reasoning should apply equally to an administrative interpretation of an agency regulation.

Solid Waste's clear statement rule is based upon understandable and significant federalism concerns, the importance of which I do not doubt. The question we must ask ourselves, however, is whether this canon of statutory interpretation applies to the case before us.

Not every colorable constitutional question triggers *Solid Waste*'s clear statement rule. Our past decisions dictate that we must "scrutinize constitutional objections to [the] agency interpretation skeptically. Only if the agency's proffered interpretation raises *serious* constitutional concerns may [we] refuse to defer . . . ." *Williams v. Babbitt*, 115 F.3d 657, 662 (9th Cir. 1997), *citing Republican Nat'l Comm. v. Fed. Election Comm'n*, 76 F.3d 400, 409 (D.C. Cir. 1996). As such, the proper approach here is to proceed directly to the merits of Petitioners' constitutional challenge, deciding whether the agency interpretation "raise[s] the sort of grave and doubtful

constitutional questions" that could lead us to "invalidate the regulations in order to save the statute from unconstitutionality." *Rust*, 500 U.S. at 191 (internal quotation marks omitted); *see also United States v. Deaton*, 332 F.3d 698, 704-08 (4th Cir. 2003) (construing the *Solid Waste* canon in light of *Rust* and deciding the disputed constitutional question to determine if it is serious enough to warrant requiring a clear statement). Only if the Attorney General's proposed interpretation would likely render the statute unconstitutional do we apply *Solid Waste*'s clear statement canon. *See Williams*, 115 F.3d at 663 ("*Rust* . . . limits this intrusion on agency power to situations where it's absolutely necessary."). Applying these principles, we should not require a clear statement in this case because controlling precedent compels the conclusion that the Attorney General's interpretation did not invoke "the outer limits" of Congress's Commerce Clause power. *Solid Waste*, 531 U.S. at 172; *see also Republican Nat'l Comm.*, 76 F.3d at 409 ("Because we can easily resolve the [constitutional] challenges through the application of controlling precedent . . . , we do not face the sort of serious constitutional questions 'that would lead us to assume Congress did not intend to authorize the [regulation's] issuance.' " (quoting *Rust*, 500 U.S. at 191)).

The Commerce Clause empowers Congress to regulate (1) "the use of the channels of interstate commerce"; (2) "the instrumentalities of interstate commere, or persons or things in interstate commerce"; and (3) "those activities that substantially affect interstate commerce." *United States v. Lopez*, 514 U.S. 549, 558-59 (1995). Our court has long recognized that "the Commerce Clause empowers the federal government to regulate prescription drugs," *In re Grand Jury Proceedings*, 801 F.2d 1164, 1169 (9th Cir. 1986) (per curiam); *accord Rosenberg*, 515 F.2d at 198. We have steadfastly upheld the Controlled Substances Act against Commerce Clause challenges, even in cases involving wholly intrastate activity. *See, e.g.*, *United States v. Tisor*, 96 F.3d 370, 375 (9th Cir. 1996); *United States v. Kim*, 94 F.3d 1247, 1250 (9th Cir. 1996). *But*

see Raich v. Ashcroft, 352 F.3d 1222, 1227-28 (9th Cir. 2003) (stating that the Controlled Substances Act, as applied to "the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to a valid California state law," likely exceeded Congress's Commerce Clause power).

Turning to the specific issue raised here—whether the prescription or dispensation of controlled substances to assist suicide substantially affects interstate commerce—we base our assessment on four factors:

> 1) whether the statute in question regulates commerce or any sort of economic enterprise; 2) whether the statute contains any express jurisdictional element which might limit its reach to a discrete set of cases; 3) whether the statute or its legislative history contains express congressional findings that the regulated activity affects interstate commerce; and 4) whether the link between the regulated activity and a substantial effect on interstate commerce is attenuated.

United States v. McCoy, 323 F.3d 1114, 1119 (9th Cir. 2003) (internal quotation marks omitted). Of these four factors, the first and last are most important. *Id.*

The Ashcroft Directive clearly satisfies *McCoy*'s first and the last criteria. The Ashcroft Directive regulates economic transactions: physicians generally prescribe and dispense controlled substances for a fee. There is no indication here, as there was in *Raich* with regards to medicinal marijuana, that drug-induced physician-assisted suicide "does not involve [the] sale, exchange, or distribution" of controlled substances. *Raich*, 352 F.3d at 1229. The link between these transactions and their effect on interstate commerce is not attenuated simply because relatively few Oregonians use controlled substances for assisted suicide. We evaluate whether an activity's

link to interstate commerce is attenuated by assessing whether its effect on interstate commerce is sufficiently *direct*, *Solid Waste*, 531 U.S. at 195; *McCoy*, 323 F.3d at 1123-24, and we assess individual provisions as "part[s] of a wider regulatory scheme" (i.e., the Controlled Substances Act), which regulates a field of drug-related activity that has "a 'substantial affect' on interstate commerce," *Tisor*, 96 F.3d at 375. Here Congress naturally and directly reduces the amount of a controlled substance that flows through the interstate channels when it prohibits the substance's distribution for a particular use. Thus, the link between drug prescriptions and interstate commerce is sufficiently direct and substantial even if the drugs ultimately are used in intrastate activities such as physician-assisted suicide and the activities' disaggregated effect on interstate commerce is small.

Because the Ashcroft Directive satisfies *McCoy*'s first and last factors, we need not consider whether it meets the other, less important ones. *See McCoy*, 323 F.3d at 1119 (explaining that the second and third factors may "aid" the court's analysis, but "are ordinarily not, in themselves, dispositive"); *id.* at 1126-27 (observing that legislative history is "neither necessary nor conclusive" in Commerce Clause analysis). Under *McCoy*, Congress' Commerce Clause power to prohibit physicians from prescribing controlled substances to assist suicide is not open to serious question. That ends the matter in this circuit and, of course, for this case.

The majority cannot have it otherwise. Their argument that "*direct* control of medical practice in the states is beyond the power of the federal government" misses the point. *Linder v. United States*, 268 U.S. 5, 18 (1925) (emphasis added). Unless and until the Supreme Court directs us differently, our opinions and other binding precedent compel the conclusion that Congress acts comfortably within its Commerce Clause power when it regulates the prescription and dispensation of controlled substances. *See Minor v. United States*, 396 U.S. 87, 98 n.13 (1969) (stating that "a flat ban on certain [drug

transactions] . . . is sustainable under the powers granted Congress" by the Commerce Clause); *Reina v. United States*, 364 U.S. 507, 511 (1960) (referring to Congress's "undoubted power to enact the narcotics laws"); *Tisor*, 96 F.3d at 375 ("[D]rug trafficking is a commercial activity which substantially affects interstate commerce."); *Kim*, 94 F.3d at 1250 n.4 (recognizing that Congress may regulate controlled substances pursuant to the Commerce Clause even when legislation "intrudes into an area traditionally regulated by states"); *Rosenberg*, 515 F.2d at 198 (dubbing an analogous constitutional challenge "singularly unpersuasive"). General Ashcroft's interpretation of 21 C.F.R. § 1306.04(a) does not, therefore, "invoke[ ] the outer limits of Congress' power," *Solid Waste*, 531 U.S. at 172, the clear statement rule does not apply, and we must evaluate the Ashcroft Directive according to ordinary standards of deference.

D.

The Petitioners contend that the Ashcroft Directive constitutes an arbitrary and capricious interpretation of section 1306.04(a)'s "legitimate medical practice" requirement. General Ashcroft's determination is arbitrary and capricious, they argue, because he failed to examine the "wealth" of substantive data documenting the Oregon Act's effect on public health and safety. They point to a collection of studies which indicate that the Oregon Act's procedures have not been used disproportionately by the poor, uneducated, or uninsured. "Normally, an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983).

Although these empirical studies might be socially important, their findings were not an "important aspect of the problem" confronted by the Attorney General. General Ashcroft had before him a single question: whether physician-assisted suicide is a "legitimate medical purpose" as defined in exist-

ing case law, federal policy, general state law, and medical opinion. Evidence that Oregon physicians used the Oregon Act's procedures disproportionally against the poor, uneducated, or uninsured could have strengthened his conclusion that physician-assisted suicide is not a "legitimate medical purpose," but it does not follow that the absence of such evidence means physician-assisted suicide is a "legitimate medical practice." Thus, whether the Oregon Act provided adequate safeguards for vulnerable groups was not a sufficiently important aspect of the Attorney General's inquiry to render the Ashcroft Directive an arbitrary and capricious agency action.

Furthermore, Petitioners' assertion that General Ashcroft "entirely failed to consider" Oregon's position on the social benefits of physician-assisted suicide is plainly false. The Attorney General based his decision on a memorandum from the Office of Legal Counsel, which considered, but rejected, Oregon's position in favor of existing case law, federal policies and practices, the majority state position, and the dominant views of the American medical and nursing professions. *See* Memorandum from Shelden Bradshaw, Deputy Assistant Attorney General, and Robert J. Delahunty, Special Counsel, *Memorandum for the Attorney General: Whether Physician-Assisted Suicide Serves a "Legitimate Medical Purpose" Under the Drug Enforcement Administration's Regulations Implementing the Controlled Substances Act* (Memorandum) 5-14 (June 27, 2001). Thus, Petitioners have not shown that General Ashcroft's decision to reject the Oregon Act's permissive approach to physician-assisted suicide was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(a).

III.

Having demonstrated the fallacies of the foregoing challenges to the Ashcroft Directive, I now consider what standard of review this court should apply when assessing the

Ashcroft Directive's validity. The degree of deference we accord an interpretive rule depends upon whether the rule construes a statute or an agency regulation.

If the Ashcroft Directive represents a statutory interpretation, it enjoys deference as defined in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). *Omohundro v. United States*, 300 F.3d 1065, 1067-68 (9th Cir. 2002). Under *Skidmore*, "[t]he weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Skidmore*, 323 U.S. at 140. Especially relevant under *Skidmore* is the fact that the Ashcroft Directive reverses the agency's earlier interpretation. *See Cmty. Hosp. of the Monterey Peninsula v. Thompson*, 323 F.3d 782, 792 (9th Cir. 2003) ("An agency interpretation . . . which conflicts with the agency's earlier interpretation is entitled to considerably less deference than a consistently held agency view." (internal brackets, quotation marks, and citation omitted)). The agency "is not disqualified from changing its mind," however, "and when it does, the courts still sit in review of the administrative decision and should not approach the statutory construction issue *de novo* and without regard to the administrative understanding of the statutes." *NLRB v. Local Union No. 103, Int'l Ass'n of Bridge, Structural & Ornamental Iron Workers*, 434 U.S. 335, 351 (1978).

If the Ashcroft Directive interprets an agency regulation, rather than the Controlled Substances Act itself, we must accord it "substantial deference." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). Under this highly deferential standard,

> [o]ur task is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency's interpretation must be given controlling weight unless it is plainly errone-

> ous or inconsistent with the regulation. In other words, we must defer to the Secretary's interpretation unless an alternative reading is compelled by the regulation's plain language or by other indications of the Secretary's intent at the time of the regulation's promulgation.

Id. (internal citations and quotation marks omitted). Agency interpretations of regulations enjoy substantial deference even if they are inconsistent with the agency's prior interpretations. As the Supreme Court explained in *Thomas Jefferson*, an agency "is not estopped from changing a view [it] believes to have been grounded upon a mistaken legal interpretation." *Id.* at 517 (internal quotation marks and citation omitted). "[W]here the agency's interpretation of [its regulation] is at least as plausible as competing ones, there is little, if any, reason not to defer to its construction." *Id.* (internal quotation marks and citation omitted) (second brackets in original).

In my view, the Ashcroft Directive constitutes an interpretation of a regulation rather than a statutory interpretation. The Ashcroft Directive's single interpretive act is to "determine that assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04 (2001)." Ashcroft Directive, 66 Fed. Reg. at 56,608. The Petitioners point to General Ashcroft's warning that prescribing a controlled substance to assist suicide may render a physician's registration subject to suspension or revocation under section 824(a)(4). This statement was not an *interpretation* of the Controlled Substances Act, however, but an explanation of the logical consequences flowing from General Ashcroft's interpretation of 21 C.F.R. § 1306.04. If assisting suicide is not a "legitimate medical purpose," the direct result is that a physician cannot prescribe controlled substances for this purpose without violating Controlled Substances Act section 829 and thereby risking suspension or revocation of their registration under sections 823 and 824. *See* 21 U.S.C. § 823(f)(4) (stating that a physician's violation of federal law is relevant

to determine if his registration is inconsistent with the public interest); *id.* § 824(a)(4) (providing that a physician's registration may be revoked for acts inconsistent with the public interest under section 823). Petitioners' contention that General Ashcroft was interpreting the word "practitioner" under 21 U.S.C. § 829 is likewise wrong. Nothing in the Ashcroft Directive turns upon the definition of "practitioner." Thus, the Ashcroft Directive qualifies for *Thomas Jefferson*'s highly deferential standard of review.

Applying the *Thomas Jefferson* standard, I have no trouble upholding the Ashcroft Directive from Petitioners' attack. As the Office of Legal Counsel concluded:

> [T]he overwhelming weight of authority in judicial decisions, the past and present policies of nearly all of the States and of the Federal Government, and the clear, firm and unequivocal views of the leading associations within the American medical and nursing professions, establish that assisting in suicide is not an activity undertaken in the course of professional medical practice and is not a legitimate medical purpose. Indeed, we think it fair to say that physician-assisted suicide should not be considered a *medical* procedure at all . . . . It is plainly a fallacy to assume that a procedure must be "medical" because it is performed by a physician rather than, say, by a family member, or because it involves the use of a drug that a physician has prescribed.

Memorandum at 13-14; *see also* Ashcroft Directive, 66 Fed. Reg. at 56,608 (stating that the Memorandum "sets forth the legal basis for my decision"). In *Glucksberg*, the Supreme Court offered a similar assessment: "opposition to and condemnation of suicide—and, therefore, of assisting suicide—are consistent and enduring themes of our philosophical, legal, and cultural heritages. More specifically, for over 700 years, the Anglo-American common-law tradition has pun-

ished or otherwise disapproved of both suicide and assisting suicide." *Glucksberg*, 521 U.S. at 711 (internal citations omitted). Given this overwhelming historical, legal, and medical consensus that physician-assisted suicide is not a legitimate medical purpose, the Ashcroft Directive clearly satisfies *Thomas Jefferson*. Therefore, I would defer to the Ashcroft Directive's conclusion that physician-assisted suicide is not a "legitimate medical practice" under 21 C.F.R. § 1306.04(a).

IV.

Although I concur with the majority's brief discussion on justiciability and its conclusion as to our jurisdiction, I write separately to address the latter, as it is contested by the parties and resolved improperly by the district court, yet given scant attention by the majority. The majority suggests that *Hemp Industries Association v. DEA*, 333 F.3d 1082 (9th Cir. 2003), is dispositive, but *Hemp Industries* declined to answer the precise question at issue here; that is, we left open "whether we would have original jurisdiction over an interpretive rule." *Id.* at 1085. A more thorough analysis is therefore needed to determine whether the Ashcroft Directive, which by its terms is an interpretive rule, is a "final determination" within the meaning of 21 U.S.C. § 877 over which we would have jurisdiction.

Section 877 provides that "[a]ll final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved." 21 U.S.C. § 871. The section provides us original jurisdiction where "any person aggrieved by a final decision of the Attorney General" seeks "review of the decision." *Id.* Significantly, the Ashcroft Directive echoes the language of this provision by "advis[ing] . . . that the original DEA *determination* is reinstated and should be implemented." Ashcroft Directive, 66 Fed. Reg. 56,608 (emphasis added); *see also, e.g.*, *id.* ("I hereby *determine* that assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R.

§ 1306.04 (2001) . . . ." (emphasis added)); *id.* ("I hereby direct the DEA . . . to enforce and apply this *determination* . . . ." (emphasis added)). Although helpful, the Attorney General's choice of words does not necessarily mean his "determination" is "final."

The district court held that the Ashcroft Directive is not "final" because General Ashcroft kept his own counsel, gave no notice or opportunity for comment, took no evidence, and did not produce an administrative record. As the district court observed, there is a paucity of appellate court decisions analyzing section 877's requirements for review. In order to respond to the district court's argument, therefore, I must reason by analogy and look to general principles of administrative law formulated under the APA. *See U.S. W. Communications, Inc. v. Hamilton*, 224 F.3d 1049, 1054-55 (9th Cir. 2000) (using the APA's definition of "final" to interpret "final orders" under the Hobbs Act). For an agency action to be final under the APA, the agency need not obtain outside advice. It need not give notice and an opportunity to comment. *Guadamuz v. Bowen*, 859 F.2d 762, 771 (9th Cir. 1988). Absent a contrary command under the governing statute, the agency need not produce an administrative record, especially for review of purely legal questions such as those in the case before us.

As the Supreme Court held in *Bennett v. Spear*, 520 U.S. 154 (1997), an agency action is "final" under the APA if it satisfies two criteria: (1) "the action must mark the consummation of the agency's decision making process—it must not be of a merely tentative or interlocutory nature"; and (2) "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* at 177-78 (internal citations and quotation marks omitted). In evaluating whether an agency action meets these conditions, relevant considerations include: (a) whether the action is a "definitive statement of an agency's position," (b) whether it has a "direct and immediate effect on the complaining par-

ties," (c) whether it "has the status of law," and (d) whether it "requires immediate compliance." *Assn. of Am. Med. Colls. v. United States*, 217 F.3d 770, 780 (9th Cir. 2000).

As an interpretive rule, the Ashcroft Directive does not have the "force of law." *Hemp Indus. Ass'n*, 333 F.3d at 1087. Nevertheless, this does not necessarily preclude the Ashcroft Directive from constituting a "final determination." In *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), *overruled on other grounds*, *Califano v. Sanders*, 430 U.S. 99 (1977), the Supreme Court announced that finality is to be interpreted "in a pragmatic way," meaning that even pre-enforcement regulations that merely state an agency's intentions may be final for review. *Id.* at 149-50; *see also Alaska v. EPA*, 244 F.3d 748, 750 (9th Cir. 2001) (order) (holding that the EPA's pre-enforcement order to invalidate a permit was final). Because an interpretive rule can be a final order, and because "final orders" are analytically equivalent to "final agency actions," *U.S. W. Communications*, 224 F.3d at 1055, it follows that interpretive rules can constitute final agency actions under the APA. Thus, the Ashcroft Directive may qualify as a final agency action notwithstanding the fact that it has not been enforced and does not have the force of law.

Turning to the first *Bennett* requirement, the Ashcroft Directive clearly marks the consummation of the Attorney General's decision making process even though it is a non-binding, pre-enforcement, interpretive rule. The Ashcroft Directive reflects internal agency deliberation, on a matter of public importance, and commands immediate implementation. Eschewing tentative or equivocal words, it speaks in the immediate and imperative language of final agency action. *See* Ashcroft Directive, 66 Fed. Reg. at 56,608 ("I hereby direct the DEA . . . to enforce and apply this determination . . . ."); *accord Nat'l Automatic Laundry & Cleaning Council v. Shultz*, 443 F.2d 689, 702 (D.C. Cir. 1971) (holding that "when [an agency's] interpretation is not labeled as tentative or otherwise qualified by arrangement for reconsideration"

there is "no basis" for concluding that the " 'agency action' is 'not final' for purposes of the APA and judicial review"). The Ashcroft Directive purports to be the Attorney General's interpretation, not the interpretation of an underling whose view may be overruled. *Accord Nat'l Automatic Laundry*, 443 F.2d at 701 (reasoning that "with the authoritative interpretative ruling by the [agency head,] the agency's interpretative action has come to an end, and there is no fair basis for saying this process will be disrupted by judicial review"). In addition, the Attorney General's decision to publish the Ashcroft Directive in the Federal Register, rather than simply issue a press release or send an opinion letter to a private party, indicates that the Ashcroft Directive represents the consummation of his decision-making process. For these reasons, the Ashcroft Directive clearly satisfies the first *Bennett* inquiry.

The next question under *Bennett* is whether legal consequences flow from the agency action. 520 U.S. at 178. Relevant factors include whether the agency action has a "direct and immediate effect" on the complaining parties and requires their "immediate compliance." *Am. Med. Colls.*, 217 F.3d at 780. As explained previously, an interpretive rule may be a final agency action even though it is not legally binding.

The Ashcroft Directive satisfies this second requirement as well. Although it may not have the force of law, the Ashcroft Directive significantly and immediately alters the legal landscape for Oregon physicians. *See Bennett*, 520 U.S. at 178 (holding that an agency action met this requirement because it had similar "direct and appreciable legal consequences"); *Abbott Labs.*, 387 U.S. at 152-53 (holding that where plaintiffs must either comply with unfavorable regulations immediately or "risk serious criminal and civil penalties," the agency action satisfies this requirement). The Ashcroft Directive "direct[s] the DEA, effective upon publication of this memorandum in the Federal Register, to enforce and apply" the Attorney General's interpretation of 21 C.F.R. § 1306.04(a). This instruction created direct and immediate consequences

for physicians who wish to prescribe controlled substances for assisted suicide.

It is of no moment that physicians will not experience the Ashcroft Directive's concrete legal effects unless they actually choose to prescribe controlled substances for assisted suicide. An agency action can be final even if its concrete legal effects are contingent upon a future event. *City of Fremont v. FERC*, 336 F.3d 910, 914 (9th Cir. 2003) (concluding that agency orders that attach legal consequences to future proceedings are final for judicial review). The Ashcroft Directive requires the physicians' immediate compliance. Thus, it satisfies *Bennett*'s second requirement for finality.

Because the Ashcroft Directive constitutes a final agency action under *Bennett*, the instant petition for review falls squarely within this court's original jurisdiction. I therefore concur in the majority's assessment that the district court was without jurisdiction and the petition should be considered transferred to this court under 28 U.S.C. § 1631.

V.

Although I am convinced of the merits of my legal argument, I admit that even if I persuaded one of my colleagues to join me, my opinion would not be a final chapter. Those who are uneasy with my position (as I assume Petitioners will be) should see its limited grasp. The Ashcroft Directive constitutes a final agency action, but it surely will not be the last word on physician-assisted suicide. The Ashcroft Directive does not spell the end of the public's "earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide," *Glucksberg*, 521 U.S. at 735, nor does it halt states' "extensive and serious evaluation of physician-assisted suicide and other related issues," *Glucksberg*, 521 U.S. at 736, 737 (O'Connor, J., concurring). State legislators may supplement the Ashcroft Directive's sanctions, and they may authorize alternative methods for assist-

ing suicide that do not involve the prescription of controlled substances.

More to my point, the Ashcroft Directive is not even an immutable expression of *federal* policy. A change in presidential administrations or a shift in the current President or Attorney General's perspective might precipitate the Ashcroft Directive's rescission. Certainly, Congress is free to enact legislation limiting or counteracting the Ashcroft Directive's effects. Although opinions differ over the propriety of assisted suicide, I fully subscribe to Justice O'Connor's canny observation that there is simply "no reason to think that the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the [government]'s interests in protecting those who might seek to end life mistakenly or under pressure." *Id.* In short, we should trust the democratic process.

Thus, the discrete question before this court is a narrow one: is the Attorney General's interpretation of 21 C.F.R. § 1306.04 entitled to deference? Nothing in the Controlled Substances Act's text or legislative history authorizes the majority to deny deference to the Ashcroft Directive. As an interpretive rule, the Ashcroft Directive is not subject to the APA's notice-and-comment rulemaking procedures. It does not violate the Controlled Substances Act's nonpreemption provision. It neither exceeds the Attorney General's statutory authority under the Controlled Substances Act nor "push[es] the limit of congressional authority" under the Commerce Clause. *Solid Waste*, 531 U.S. at 173. Petitioners have not demonstrated that the Ashcroft Directive's interpretation of section 1306.04 is arbitrary and capricious. For these reasons, firmly established principles of administrative law formulated by the Supreme Court and our court command us to defer to the Attorney General's interpretation of section 1306.04.

Therefore, I dissent.